

Members:

Rep. Charlie Brown, Chairperson
Rep. Susan Crosby
Rep. Craig Fry
Rep. Vaneta Becker
Rep. Karen Burkhardt
Rep. Phyllis Pond
Sen. Marvin Riegsecker
Sen. Beverly Gard
Sen. Robert Jackman
Sen. Glenn Howard
Sen. Vi Simpson
Sen. Cleo Washington



INTERIM STUDY COMMITTEE ON HEALTH ISSUES

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Authority: Legislative Council Resolution 2-1998

MEETING MINUTES

Meeting Date: July 29, 1998
Meeting Time: 10:00 A.M.
Meeting Place: State House, 200 W. Washington St.,
the House Chambers
Meeting City: Indianapolis, Indiana
Meeting Number: 3

Members Present: Rep. Charlie Brown, Chairperson; Rep. Susan Crosby; Rep. Karen Burkhardt; Rep. Phyllis Pond; Sen. Marvin Riegsecker; Sen. Beverly Gard; Sen. Glenn Howard; Sen. Cleo Washington.

Members Absent: Rep. Craig Fry; Rep. Vaneta Becker; Sen. Robert Jackman; Sen. Vi Simpson.

Representative Charlie Brown called the meeting to order at 10:20 a.m. and announced that the meeting would consist of a discussion of issues related to the use of latex gloves by health care providers.

Representative R. Michael Young, District 92

Representative Young stated that he introduced legislation (HB 1085-1998) during the 1998 session concerning the issue of latex gloves. Most of the general population is not aware of the problems associated with latex allergies. About 1% to 6% of the general population and about 8% to 12% of regularly exposed health care workers are sensitized to latex according to scientific literature reported in the NIOSH ALERT

(DHHS (NIOSH) Publication No. 97-135).¹ The powder in latex gloves can cause latex proteins to be released in the air and breathed in by others in the vicinity. There have been reported cases of individuals who have died from latex allergies. Rep. Young pointed out that hospitals prohibit smoking in the facilities and some wards do not allow flowers because of the pollen. However, hospitals and health professionals know about latex allergies but some do not use reduced protein or non-latex gloves. The cost of substitute gloves is comparable to powdered latex gloves.

Responding to Committee questions, Rep. Young stated that he is aware of the argument that latex gloves provide the wearer with better tactile sensation than other gloves. This extra sensitivity may be needed in areas like surgery but most health care workers do not need that extra sensitivity to perform their jobs (e.g. drawing blood).

Glenda Murray, Registered Nurse, Indianapolis, Indiana

Ms. Murray stated that she is unable to practice as a Registered Nurse because of her latex allergy. The use of latex is very prevalent in our society. She has had to avoid certain places that most people would not think would be dangerous to a person with latex allergies. She has had to avoid certain grocery stores and day care centers because of the exposure to latex. Though she has tried to change careers she has not found an office that can accommodate her need to be away from latex. She has worked with the Indiana Dental Association to help find a dentist that can accommodate her but has been unable to find a dentist. Her only hope to get two teeth fixed is at Methodist Hospital - if she can get approval from her insurance company. There are non-latex gloves available that are as sensitive as latex gloves. Studies have indicated that 6.4% of the general population is sensitive to latex. In recent years stories concerning latex allergies have appeared in the Indianapolis Star newspaper and Indianapolis Monthly magazine.

Ed Popchef, Indiana Dental Association

Mr. Popchef acknowledged that the Indiana Dental Association has been working with Ms. Murray to find her appropriate dental services. Due to the severity of her latex allergy she must be treated in a hospital setting. During the legislative session the Indiana Dental Association opposed HB 1085-1998. However, since the session the Indiana Dental Association has been studying the issue and has worked to educate its members about latex allergies.

Chakwan Siew, Ph.D., Director, Toxicology Department, Research Institute of Scientific Affairs Division, American Dental Association

Doctor Siew stated that the American Dental Association is very interested in the

¹ This document and other articles concerning latex allergies are on file in the Legislative Information Center, Room 230, Statehouse, Indianapolis, Indiana. The telephone number of the Legislative Information Center is (317) 232-9856, and the mailing address is 200 W. Washington St., Suite 301, Indianapolis, Indiana 46204-2789.

issues involved with latex allergies. Dentists and other health care workers are required to use gloves that provide barrier protection against HIV and other diseases. The allergy is classified into three types, from mild skin irritation to severe reaction. A recent health screening discovered that 6.1% of the population has an allergy to the proteins in latex. There are about 265 different proteins in latex, but it is not known which proteins are responsible for the allergy. Banning the use of powder in latex gloves may or may not reduce latex allergies. More scientific research in this area is needed. Various federal agencies are studying latex allergies and other types of gloves' effectiveness as barrier protection. Doctor Siew stated that a new national standard concerning latex gloves will probably be issued by the Food and Drug Administration and the National Institute for Occupational Safety and Health within the next year. Dr. Siew distributed an article to Committee members.²

Tim Kennedy, Indiana Hospital and Health Association

Mr. Kennedy stated that latex allergies are a serious issue with serious risks to certain people. Hospitals are aware of the problems associated with latex but are caught between the science and governmental agencies. The Occupational Safety and Health Administration (OSHA) requires that latex gloves be used when in contact with blood pathogens. Mr. Kennedy read several excerpts from "Medical Glove Powder Report" (Center for Devices and Radiological Health, September 1997)³ including the following concerns regarding the banning of powdered medical gloves:

- The effect of powder-free gloves on user preferences and needs for qualities (such as tactile sensation, etc.) are largely unknown.
- Conversion to powder-free gloves would most likely result in increased costs to the U.S. health care system.
- It is not clear that the amount of particulates need to be reduced to the "powder-free" level in order to offer an acceptable level of protection from adverse health effects. A ban does not address natural latex protein levels.

Mr. Kennedy remarked that OSHA is supposed to issue new recommendations, which will have the force of law, by the end of the year. He did not want Indiana to implement policies that may end up being in conflict with OSHA regulations. Also, the FDA is scheduled to have latex labeling requirements issued by this September.

Mr. Kennedy then presented the results of a survey the Indiana Hospital and Health Association had given to Indiana acute care and psychiatric hospitals.⁴ Some of the

² "Natural Rubber Latex Hypersensitivity" is on file with the Legislative Information Center (see footnote 1).

³ This document is on file with the Legislative Information Center (see footnote 1).

⁴ This document is on file with the Legislative Information Center (see footnote 1).

results included the following:

- 68% of the hospitals have banned, or are planning to ban, the use of powdered latex gloves.
- 83% of the hospitals currently have, or are in the process of implementing, policies for identifying employees who are latex sensitive.

Mr. Kennedy distributed a copy of the "Latex Litigation Report"⁵ to Commission members and mentioned that health malpractice insurance carriers have issued bulletins to their members to educate them on latex allergies. Mr. Kennedy summarized by saying that no state legislation is needed because the free market is working well to address this problem.

Steve Wintermeyer, M.D., Clarian Health Partners, Inc.

Dr. Wintermeyer indicated that 6-12% of health care workers have a sensitivity to the proteins in latex. Most of these people have a minor sensitivity to the skin. A minority have severe reactions. A balanced approach is needed before requiring a change from latex gloves. Latex gloves provide barrier protection to blood born pathogens. Alternative gloves may provide proper protection but studies should be conducted to assure that the new gloves provide the protection needed for HIV and hepatitis. Other factors that must be considered are the tactile sensation needed by the health care worker and the needs of the patient. At Clarian Health all employees are screened for latex allergies. Those employees that test positive are sent to an allergist and a plan is developed to limit the employee's exposure to latex. Currently, Methodist Hospital in Indianapolis has almost 100 employees with latex allergies. Indiana University Hospital, like other hospitals in the state, is voluntarily reducing its use of latex products. Dr. Wintermeyer distributed documents to the Committee.⁶

Joe Loftus, Barnes & Thornburg for Allegiance Health Care Corporation

Mr. Loftus testified that Allegiance Health Care Corporation distributes over 300,000 medical products. They manufacture some of the products themselves. Each year they make over 1 billion different types of gloves, including surgical gloves. About 80% of these gloves are powdered latex gloves. Allegiance supports appropriate government regulation in this area. Various federal agencies have already begun to examine the problem of latex allergies and new regulations are expected soon. Existing OSHA regulations require latex gloves for barrier protection. Currently, latex gloves are deemed to be the most effective glove for barrier protection. Newer alternative gloves may be as effective, but they must undergo testing. Mr. Loftus then briefly outlined the

⁵ This document is on file with the Legislative Information Center (see footnote 1).

⁶ "A Guide to the Management of Patients with Latex Allergies" and a section of the Federal Register concerning medical devices containing rubber is on file with the Legislative Information Center (see footnote 1).

process involved in manufacturing latex gloves. The machine that molds the glove has powder on it to allow the glove to be removed from the mold. If the glove is to become a powdered latex glove, powder is added to the inside of the glove. If the glove is to become a reduced powder latex glove the glove is rinsed in a chlorine solution. The chlorine damages the properties of the latex glove (e.g. harder to put on, stiffer, not as sensitive, tear easier). He concluded by stating that before any action is taken to require alternative gloves to be used the following factors should be considered: (1) are alternatives readily available; (2) will there be any added cost; and (3) are the alternatives as good as latex gloves.

Andrew Saxon, M.D., Chief, Division of Clinical Immunology and Allergy, U.C.L.A. School of Medicine

Dr. Saxon stated that latex allergies are a real concern to the medical community. The NHANES III study (National Health & Nutrition Examination Survey), which was conducted by the National Center for Health Statistics, found that health care workers, including those who wear gloves, are not at any greater risk of latex sensitization than other segments of the general population. Just because an individual tests positive for a latex allergy does not mean the person will manifest an adverse reaction. The majority of people who have a latex allergy have symptoms no worse than a rash. There are over 200 different proteins found in latex. Only a few of these proteins cause allergic reactions. One problem is that different people may be allergic to different proteins in the latex. Manufacturers have reduced the amount of proteins in latex gloves by about 90%. While the number is steadily being reduced it will never reach 0%. Latex gloves are a medical device. Like any medical device it should be used when needed and used correctly. Penicillin causes more reactions than latex. Penicillin is still used though other antibiotics are available. The medical community has learned to identify people who are allergic to penicillin. Like penicillin, policies need to be established that identify and protect people who are latex sensitive.

James M. Zieba, Director, Government Relations, Indiana State Medical Association

Mr. Zieba stated that more scientific studies are needed concerning allergies related to powdered latex gloves and the safety of alternative gloves, especially concerning barrier protection. The decision on which glove to use should be left with the physician. Educating the medical community is the key to successfully addressing the latex allergy problem. Mr. Zieba remarked that the Indiana State Medical Association has provided and will continue to provide information concerning latex allergies to the medical community.

While answering questions from Committee members, Mr. Zieba stated that if science demonstrates that alternative gloves are appropriate to use and substitute, then the medical community should use the appropriate glove.

Representative Michael Young was asked to give closing remarks to the Committee. He made the following points:

- The Mayo Clinic has already stopped using latex gloves.
- The New York state legislature has passed a bill recommending that the Department of Health review existing scientific research regarding allergic reactions to natural rubber latex products and issue guidelines in consultation with health care providers for a latex management program in health care settings.
- Legislation is not needed for the health care professionals and hospitals who are doing what they should, but for the minority that are not.

Chairman Brown adjourned the meeting at 11:55 a.m.